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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,976	10/02/2000	Michael E. Kafrissen	ORT-1316	7964

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EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/677,976	Applicant(s) KAFRISSEN ET AL.	
	Examiner Robert M DeWitty	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 21-23 are pending in the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "prevention of pregnancy and treatment of any subject, does not reasonably provide enablement for subjects whose members are afflicted/predisposed at a higher than normal incidence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01(a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

Nature of the Invention. All of the rejected claims are drawn to treating members afflicted/predisposed at a higher than normal incidence. The nature of the invention is extremely complex in that it encompasses preventing cervical dysplasia or cervical carcinoma in subjects to whom have a higher than normal incidence to become

afflicted. How does one determine the subjects whom oral contraceptives are indicated at a higher than normal incidence, what is the normal incidence of indication for oral contraceptives, what does higher than normal mean, who are the population predisposed to become afflicted with cervical dysplasia or cervical carcinoma, how to determine the population predisposed to become afflicted with cervical dysplasia or cervical carcinoma in subjects who have a higher than normal incidence to become afflicted. How does one determine the subjects to whom oral contraceptives are indicated at a higher than normal incidence?

Breath of the claims. The complex nature of the claims is greatly exacerbated by the breadth of the claims. The claims encompass prevention of cervical dysplasia or cervical carcinoma. The claim to prevention would imply that the disease prevented is not just one of the many symptoms. Further, how does one determine prevention has been obtained? The specification does not provide any data to support prevention in a subject to whom oral contraceptives are indicated at a higher than normal incidence.

Guidance of the Specification. The guidance by the specification speaks on how to administer the compound to a subject in order to treat or prevent cervical dysplasia or cervical carcinoma. The guidance provided is not directed to how to determine the subject to whom oral contraceptives are indicated at a higher than normal incidence. The specification does not provide any working examples of subjects to whom oral contraceptives are indicated at a higher than normal incidence, or any working examples to determine the subjects.

Predictability of the Art. The lack of significant guidance from the specification or the prior art with regard to the actual identification of these subjects makes practicing the instant invention unpredictable in terms of the treatment or prevention of cervical dysplasia or cervical carcinoma.

The State of the Art. The actual etiology of how one becomes afflicted is not fully understood and with cervical dysplasia or cervical carcinoma the specification does not give any indication of the agent that causes cervical dysplasia or cervical carcinoma. Rather, the specification and prior art guidance on how to treat the individual taking oral contraceptives.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al. ("Folic Acid and the Pill") further in view of Jackson et al. (U.S. Pat. No. 5,654,011).

Wood teaches the administration of folic acid with an oral contraception. Wood explicitly teaches that oral contraceptives interfere with the absorption and metabolism of **polyglutamate** but that folic acid (monoglutamate) is not affected (page 543). Wood further provides studies of women taking folic acid with oral contraception (most notably

at page 539, 540). Wood then continues to provide results from his studies whereby women were taking folic acid and oral contraceptives. However, Wood does not teach that folic acid is used in a sufficient amount to treat or prevent cervical dysplasia or cervical carcinoma.

Jackson teaches dietary supplements to supplement the needs of women and preventing or reducing life stage associated health risks. In an embodiment of the invention, Jackson teaches the use of 400 to 400mcg of folic acid in the supplement (col. 2, lines 34-51). Such supplement is useful in the treatment of cervical dysplasia (col. 2, line 57).

Based on the knowledge in the art, one with skill would know that folic acid is useful as a supplement for the treatment of diseases like cervical dysplasia. Motivation to utilize folic acid with a oral contraceptive would have arisen out of knowledge that oral contraceptives do not affect folic acid (monoglutamate), and a desire to address a woman's health needs during various life stages.

Response to Arguments

3. Based on Applicant's arguments presented 11/4/02 in the Appeal Brief, the previous rejections are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
February 10, 2003

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616